

What is claimed is:

1. A method of treating a human cancer patient, said patient having undergone a malignant cell debulking procedure and being at risk for disease relapse due to a population of residual malignant cells that may remain viable in said patient following said debulking procedure, comprising:
- a) providing a sample of stem cells from said patient, said sample being suitable for autologous transplantation into said patient;
 - b) performing an autologous transplant of said patient with said sample;
 - c) monitoring said patient until said patient is partially hematopoiesis recovered but is not fully immune-reconstituted;
 - d) administering to said patient an HLA-compatible, allogeneic peripheral blood leukocyte preparation having lymphocytes, in a regimen that causes a clinically significant graft-versus-malignant cell response; and
 - e) monitoring said patient for levels of malignant cells deriving from said population.

2. The method of claim 1, wherein said regimen comprises the following steps in sequence:

a) treating said patient by administration of about 10^7 cells/kg to about 10^9 cells/kg of HLA-compatible, allogeneic peripheral blood lymphocytes;

b) monitoring said patient for indications of a graft-versus-malignant cell response; and

c) if no or insufficient graft-versus-malignant cell response develops in said patient, escalating said treatment by performing at least one procedure selected from the group consisting of (1) administration of a number of HLA-compatible, allogeneic peripheral blood lymphocytes greater than the number of lymphocytes administered in step (a); (2) administration of a number of HLA-compatible, allogeneic peripheral blood lymphocytes at least as great as the number of lymphocytes administered in step (a), accompanied by administration of at least one T-cell-activating cytokine to said patient; (3) administration of HLA-compatible, allogeneic CAL's to said patient; and (4) administration of HLA-compatible, allogeneic CAL's, accompanied by administration in vivo of at least one T-cell-activating cytokine to said patient;

21 wherein more than one of said procedures is performed if no or
22 insufficient graft-versus-malignant cell response develops in said
23 patient following said first or subsequent procedure.

1 3. The method of claim 2, wherein step (a) further comprises
2 administration in vivo of at least one T-cell-activating cytokine to said patient.

1 4. A method of treating a human cancer patient, said patient having
2 undergone a malignant cell debulking procedure and being at risk for disease relapse
3 due to a population of residual malignant cells that may remain viable in said
4 patient following said debulking procedure, comprising:

5 a) providing a sample of stem cells from said patient, said
6 sample being suitable for autologous transplantation into said patient;

7 b) performing an autologous transplant of said patient with
8 said sample;

9 c) monitoring said patient until said patient is partially
10 hematopoiesis recovered but is not fully immune-reconstituted;

11 d) administering to said patient an HLA-compatible,
12 allogeneic peripheral blood leukocyte preparation having lymphocytes,
13 in a regimen that causes a mild graft-versus-host response; and

14 e) monitoring said patient for levels of malignant cells
15 deriving from said population.

1 5. The method of claim 4, wherein said regimen comprises the following
2 steps in sequence:

3 a) treating said patient by administration of about 10^7
4 cells/kg to about 10^9 cells/kg of HLA-compatible, allogeneic peripheral
5 blood lymphocytes;

6 b) monitoring said patient for indications of a mild graft-
7 versus-host response; and

8 c) if no or insufficient graft-versus-host response develops
9 in said patient, escalating said treatment by performing at least one
10 procedure selected from the group consisting of (1) administration of a
11 number of HLA-compatible, allogeneic peripheral blood lymphocytes
12 greater than the number of lymphocytes administered in step (a); (2)
13 administration of a number of HLA-compatible, allogeneic peripheral
14 blood lymphocytes at least as great as the number of lymphocytes
15 administered in step (a), accompanied by administration of at least one
16 T-cell-activating cytokine to said patient; (3) administration of HLA-
17 compatible, allogeneic CAL's to said patient; and (4) administration of
18 HLA-compatible, allogeneic CAL's, accompanied by administration of
19 at least one T-cell-activating cytokine to said patient;

20 wherein more than one of said procedures is performed if no or
21 insufficient graft-versus-host response develops in said patient
22 following said first or subsequent procedure.

1 6. The method of claim 5, wherein step (a) further comprises
2 administration in vivo of at least one T-cell-activating cytokine to said patient.

1 7. The method of claim 4, wherein said regimen comprises the following
steps in sequence:

2
3
4
5 a) administering to said patient about 10^7 cells/kg to about
6 10^9 cells/kg of HLA-compatible, allogeneic peripheral blood
7 lymphocytes and at least one T-cell-activating cytokine to said patient;;

8
9 b) monitoring said patient for signs of a mild graft-versus-
10 host response;

11
12 c) if no or insufficient graft-versus-host response develops
13 in said patient, administering about 10^7 cells/kg to about 10^9 cells/kg of
HLA-compatible, allogeneic CAL and at least one T-cell-activating
cytokine to said patient; and

d) monitoring said patient for signs of a mild graft-versus-
host response.

1 8. The method of claim 4, wherein said regimen comprises the following
2 steps in sequence:

3 a) administering to said patient about 10^5 cells/kg to about
4 10^9 cells/kg of HLA-compatible, allogeneic peripheral blood
5 lymphocytes, said HLA-compatible, allogeneic peripheral blood
6 lymphocytes comprising CAL, and at least one T-cell-activating
7 cytokine to said patient;

8 b) monitoring said patient for signs of a mild graft-versus-
9 host response;

10 c) if no or insufficient graft-versus-host response develops
11 in said patient, administering about 10^5 cells/kg to about 10^9 cells/kg of
12 HLA-compatible, allogeneic CAL and at least one T-cell-activating
13 cytokine to said patient; and

14 d) monitoring said patient for signs of a mild graft-versus-
15 host response.

1 9. The method of claim 2, 3, 5, 6, 7 or 8 wherein said cytokine is selected
2 from the group consisting of IL2, IL4, IL5, IL6, IL7, IFN α , IFN γ and TNF α .

1 10. The method of claim 4, wherein said stem cells are obtained from bone
2 marrow.

1 11. The method of claim 4, wherein said stem cells are obtained from the
2 peripheral circulation.

1 12. The method of claim 4, wherein said stem cells are obtained from fetal
2 sources selected from the group consisting of fetal tissue, fetal circulation and
3 umbilical cord blood.

1 13. The method of claim 4, wherein said malignant cells are leukemia
2 cells.

1 14. The method of claim 4, wherein said malignant cells are lymphoma
2 cells.

1 15. The method of claim 4, wherein said malignant cells are breast cancer
2 cells.

1 16. The method of claim 1 or 4, wherein said HLA-compatible cells are
2 fully HLA-matched with said patient.

1 17. The method of claim 1 or 4, wherein said HLA-compatible cells are at
2 least haploidentical with said patient.

1 18. The method of claim 1 or 4, wherein said HLA-compatible cells are
2 single HLA locus-mismatched cells from a sibling of said patient.

1 19. An article of manufacture comprising packaging material and a
2 biological cell container within said packaging material, wherein said packaging
3 material contains a label or package insert indicating that said biological cell
4 container and any contents therein are to be used in the method of claim 1 or 4.

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